

REMARKS

Claims 10, 11 and 13 are amended herein for clarity. No new matter is presented.

I. Request for Initialed Copy of PTO/SB/08

The Examiner has also returned the PTO/SB/08 Form submitted with the Information Disclosure Statements filed on June 22, 2006 and November 20, 2007. However, the Examiner crossed off the foreign references and one of the non-patent literature documents, presumably because copies of these references were not submitted with the Information Disclosure Statement as indicated in the transmittal letter filed with the IDS on June 22, 2006.

Copies of these references are submitted herewith in a Supplemental IDS. The Examiner is requested to kindly acknowledge the same and to return an initialed copy of the PTO/SB/08 Form with the next Action.

II. Election/Restriction Requirement

Applicants acknowledge that the Examiner has rejoined claims 10 and 13 for the reasons set forth at pages 2-3 of the Action. Therefore, claims 10-13 are the claims being examined.

III. Response to Objection to the Specification

The specification is objected to allegedly because line one of first page of specification, in its present form does not properly cite the application priority data. The Examiner requests that the first line of the first page of the specification indicate that the instant application claims priority to Japanese PCT.

Applicants traverse the objection to the specification as improper. Specifically, the present application is a national stage application under 35 U.S.C. § 371 and Applicants are not required to amend the first sentence of the application to reference the international application. The rules quoted by the Examiner relate to earlier applications, but the international application is not an earlier application because the national stage application and the international application are the same application and have the same filing date. Specifically, MPEP §1893.03(c)(III) states:

a national stage application submitted under 35 U.S.C. §371 may not claim benefit of the filing date of the international application of which it is the national stage since its filing date is the **>international filing date of the< international application. See also MPEP § 1893.03(b). Stated differently, since the international application is not an earlier application (it has the same filing date as the national stage), a benefit claim under 35 U.S.C. §120 in the national stage to the international application is inappropriate and may result in the submission being treated as an application filed under 35 U.S.C. §111(a). See MPEP § 1893.03(a). Accordingly, it is not necessary for the applicant to amend the first sentence(s) of the specification to reference the international application number that was used to identify the application during international processing of the application by the international authorities prior to commencement of the national stage (emphasis added).

Therefore, no amendment to the specification is required based on the above. However, the specification is amended to appease the Examiner and to expedite prosecution.

Accordingly reconsideration and withdrawal of the objection to the specification are respectfully requested.

IV. Response to Claim Rejection under 35 U.S.C. § 112, 1st Paragraph

Claims 10-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for a number of materials (See e.g., specification, Page 5, Lines 4-9) that are

"referred to as binder of the present invention" (e.g., factor G activation inhibitor co-existing with lipoarabinomannan (i.e., LAM), allegedly does not reasonably or clearly provide enablement for a step whereby the activity of said LAM in a sample containing said LAM is removed upon adding "limulus reagent" to said sample .

The Examiner states that the specification as currently presented does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with claims 10-13 especially in view of teachings of the prior art (See, Savedra, Jr, et al. 1996. Mycobacterial Lipoarabinomannan Recognition Requires a Receptor That Shares Components of the Endotoxin Signaling System. *Journal of Immunology*, Volume 157, Pages 2549-2554; NPL Reference 3 cited in Applicants' IDS filed June 22, 2006).

Applicants traverse the rejection.

It appears that the Examiner misunderstands the claimed invention. Essentially, it appears that the Examiner considers that the claimed invention to be directed to a method of using a Limulus reagent, particularly an endotoxin specific Limulus reagent, to remove the activity of LAM by contacting a LAM-containing sample with said Limulus reagent.

However the claimed invention is directed to making a LAM-containing sample non-reactive to a Limulus reagent by contacting the LAM-containing sample with one or more of the substances recited in claim 10. In other words, the purpose of the invention is to remove reactivity of LAM in the presence of a Limulus reagent, using one or more of the substances recited in claim 10 with which the LAM-containing substance is allowed to coexist, i.e., not by using a Limulus reagent. This method is fully supported and enabled by the present specification

which teaches that LAM has reactivity with a Limulus agent (see page 2, lines 14-15), which allows for measurement of LAM by contacting a LAM-containing substance with a Limulus reagent. The reactivity of LAM in the presence of a limulus reagent can be removed (or reduced) by allowing the LAM-containing substance to coexist with one or more of the substances recited in claim 10 and described in the specification at page 5, lines 4-9, for example. Further, the working examples, exemplify the claimed method such as Example 1, wherein the LAM-containing sample is subjected to the various treatment methods (i.e., allowed to coexist with various specified substances, thereby removing (or reducing) reactivity of LAM) and then contacting the treated LAM-containing sample with a Limulus reagent. The sample is then measured to determine the degree of the Limulus reaction and compared with an untreated sample. The results are provided in Table 1 which show that reactivity of LAM is reduced or removed. The claim language is slightly amended to clarify the claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

V. Response to Claim Rejection under 35 U.S.C. §112, 2nd Paragraph

Claim 13 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

According to the Examiner, the phrase, "comprising using" in Claim 13 renders the claim incomprehensible, unclear, vague and therefore, indefinite. The phrase, " comprising using " in claim 13 renders that claim indefinite because the word "using" is similar to word "use". Since the claim does not set forth any steps involved in the method/process, it is unclear what

method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

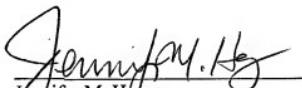
In response, claim 13 is amended to recite the specific steps of the method, thereby obviating the rejection. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

VI. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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Date: May 24, 2010